Remarks

Amendments to the Claims

Prosecution of this application was stayed due to an interference in a related application, claiming a method of treating cancer patients by removal of soluble TNF receptors from the blood or plasma. The claims in this application now have been amended to define removal of specific soluble cytokine receptors originally presented in claim 8. The dependent claims were amended as appropriate for antecedent basis.

Please note that multiple Information Disclosure Statements were filed in this application. It is believed that all references have been considered by the examiner. Please note that although surcharges were paid, not all references could be certified to have been submitted within three months of the undersigned, the assignee or the inventor having become aware of the reference. Accordingly, to the extent required for entry of these amendments or consideration of the references cited herein, the examiner is authorized to charge the fee for filing of a request for continued examination.

Rejections under 35 U.S.C. 112

The claims were rejected under 35 U.S.C. 112 on the basis that "until" was unclear. This rejection is respectfully traversed if applied to the amended claims. The claimed process involves removal of soluble cytokine receptors until the tissue is inflammed. This is observed visually by redness of the skin in the area of the tumor as well as generation of heat.

Rejection under 35 U.S.C. 103

The claims were rejected under 35 U.S.C. 103 as obvious over EP 0 183 040. This rejection is respectfully traversed.

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EP 0 183 040

This patent is the exact same disclosure as U.S. Patent No. 4,708,713 to Lentz. The '713 patent has previously been cited against the claims in this application and distinguished. The earlier patent teaches that some unknown factors, including those that are similar in size to immunoglobulin complexes (i.e., greater than 120,000 mw) as well as others, are important to remove. This unequivocally teaches away from removal of low molecular weight compounds such as soluble cytokine receptors AND teaches that the removal of many factors is required, none of which is identified as being solely responsible for protecting the tumors. Indeed, for decades and even to the present (despite completion of successful clinical trials in Europe and obtaining a CE mark allowing marketing of this technology in Europe), the conventional thinking is that cancer must be treated by killing cancer cells directly, not by removal of blocking factors in the blood, because no single factor has been determined to be responsible for cancer.

See the following section of the U.S. Patent (and in the EP):

> "In the treatment of cancer and other similar immune deficiency diseases, multiple treatments of the blood are usually necessary to effectively cure the cancer or other disease or at least reduce the tumor to a size and/or condition where it can be removed by surgery or treated by other techniques. In pregnancy, the patient is usually treated until the effects of removing or reducing the immunosuppressive factors become evident in the patient, i.e., labor begins.
>
> While the aforesaid description of the invention has been primarily directed to removing the immune blocking factors in the blood fraction having molecular weights less than 200,000, there appears to be two separate immunosuppressive or blocking fractions in the blood and other extracellular

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fluids in the body. One fraction, as previously described, has a molecular weight of less than about 200,000 and appears to be primarily responsible for blocking the cell mediated immune response. It is believed to be an IgG type immunoglobulin molecule. The other fraction has a molecular weight between about 200,000 and 1,000,000 and is believed to be an immune complex."

Allowance and issuance of the claims as amended is earnestly solicited.

Respectfully submitted,

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